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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,793	04/24/2006	Irina A Buhimschi	035394-0286	4143
54077 7590 05/29/2008 CIPHERGEN c/o FOLEY & LARDNER LLP 3000 K STREET NW SUITE 500 WASHINGTON, DC 20007				
EXAMINER				
COOK, LISA V				
ART UNIT		PAPER NUMBER		
1641				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/541,793

**Applicant(s)**

BUHIMSCI ET AL.

**Examiner**

LISA V. COOK

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature that appears to link claims 1-55 is the measurement of biomarkers or peptides (oxidized or carbonylated) in vaginal samples to determine the intra-amniotic environment. However, these methods are known and taught by the prior art. For example; US Patent #5,281,522 to Senyei et al. teaches methods for detecting normal, ectopic pregnancy, the termination of pregnancy, increased risk of preterm labor and/or the rupture of membranes via fetal fibronectin measurements in a vaginal sample. While, Buhimschi et al. (American Journal of obstetrics and gynecology, Vol. 187, No.6, 2/3/2003 through 2/8/2003, S237-S238, abstract number 654 and 655 – cited on the IDS filed 5/10/07) demonstrate a link between carbonylated amino acids and preterm labor/intra-amniotic inflammation. Therefore the technical feature recited in claims 1-55 is not a contribution over the prior art. Accordingly the groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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Group I, claim(s) 1-20, are drawn to a method for assessing the intra-amniotic environment via the measurement of a plurality of biomarkers (i.e. alpha-fetoprotein, beta-2-microglobulin) in a vaginal sample. (A 1<sup>st</sup> method utilizing a special technical feature)

Group II, claim(s) 21-37, are drawn to a method for assessing the intra-amniotic environment via the measurement of one or more oxidized or carbonylated peptides in a vaginal sample. (A 2<sup>nd</sup> method utilizing a special technical feature)

Group III, claim(s) 38 and 55, are drawn to a method for spectra analysis and comparison of at least two vaginal samples by mass spectrometry. (A 3<sup>rd</sup> method utilizing a special technical feature)

Group IV, claim(s) 39-49, are drawn to kits comprising substrates for analysis of vaginal samples. (A product comprising a special technical feature)

Group V, claim(s) 50-54, are drawn to a method for identifying spectra analysis and comparison of vaginal samples by mass spectrometry. (A 4<sup>th</sup> method utilizing a special technical feature)

3. The inventions listed as Groups I through V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Under PCT rules Applicant is entitled to an examination of one of the combination groupings: (1) a product, a method of using said product and a method of producing said product. The instant claims are directed to multiple methods and a product. Accordingly, Applicant must select one for further prosecution.

4. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I through V is not totally inclusive, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Species Election***

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

*If Applicants elect the invention of Group I or Group II the following species election is also required:*

The species are as follows:

- A.** As to Group I, Applicant must select a single biomarker indication for consideration (select either a-d).
- a. Claim 3 (measuring rupture of the fetal membrane),
  - b. Claim 4 (measuring intra-amniotic infection),
  - c. Claim 5 (measuring intra-amniotic inflammation), or
  - d. Claim 6 (measuring fetal lung maturation).

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**B.** As to Group I, Applicant must select a single biomarker for consideration (select either a-g).

- a. Claim 7 – alpha-fetoprotein,
- b. Claim 7 – fetal fibronectin,
- c. Claim 7 – insulin-like growth factor binding protein-1,
- d. Claim 7 – prolactin,
- e. Claim 7 – human placental lactogen,
- f. Claim 8 – beta-2-microglobulin, or
- g. Claim 8 – cystatin-C

**C.** As to Group I, Applicant must select a single detection method for consideration (select either a-b).

- a. Claim 10 – ELISA, or
- b. Claims 11-14 - SELDI

**D.** As to Group I, Applicant must select a single recommendation of treatment for consideration (select either a-f).

- a. Claim 18 – antibiotic treatment,
- b. Claim 18 - tocolytic treatment,
- c. Claim 18 – anti-inflammatory treatment,
- d. Claim 18 – antioxidant treatment,
- e. Claim 19 – inducing labor, or
- f. Claim 20 – cesarean section

**E.** As to Group II, Applicant must select a single detection method for consideration (select either a-c).

- a. Claim 23 – ELISA,
- b. Claims 24-27 – SELDI, or
- c. Claim 28 – pattern recognition analysis

**F.** As to Group II, Applicant must select a single recommendation of treatment for consideration (select either a-f).

- a. Claim 32 – antibiotic treatment,
- b. Claim 32 - tocolytic treatment,
- c. Claim 32 – anti-inflammatory treatment,
- d. Claim 32 – antioxidant treatment,
- e. Claim 33 – inducing labor, or
- f. Claim 34 – cesarean section

6. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The claims are deemed to correspond to the species listed above in the following manner: Each of the species are independent and distinct requiring separate search and considerations. The following claim(s) are generic: 1-2, 9, 15-17, 21-22, 29-31, and 35-55.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species is directed to methods requiring independent and distinct reagent compositions, assay, and method formats.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.



11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

*Lisa V. Cook*  
*Patent Examiner*  
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*5/23/08*

/Lisa V. Cook/  
Examiner, Art Unit 1641